

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>P03-0115PCT</b>	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. <b>PCT/JP2004/012424</b>	International filing date (day/month/year) <b>23.08.2004</b>	Priority date (day/month/year) <b>21.08.2003</b>	
International Patent Classification (IPC) or national classification and IPC <b>C12N15/12, A61K35/76, 48/00, A61P29/00, C12N1/15, 1/19, 1/21, 5/10</b>			
Applicant <b>Locomogene, Inc.</b>			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input checked="" type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) <u>1</u>, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>
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Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/012424

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following \_\_\_\_\_, which is the language of a translation furnished for the purposes of:

international search (Rule 12.3 and 23.1(b))  
 publication of the international application (Rule 12.4)  
 international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished  
 the description:  
 pages \_\_\_\_\_ as originally filed/furnished  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the claims:  
 nos. \_\_\_\_\_ as originally filed/furnished  
 nos.\* \_\_\_\_\_ as amended (together with any statement) under Article 19  
 nos.\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
 nos.\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the drawings:  
 sheets \_\_\_\_\_ as originally filed/furnished  
 sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
 sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

the description, pages \_\_\_\_\_  
 the claims, nos. \_\_\_\_\_  
 the drawings, sheets/figs \_\_\_\_\_  
 the sequence listing (*specify*): \_\_\_\_\_  
 any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages \_\_\_\_\_  
 the claims, nos. \_\_\_\_\_  
 the drawings, sheets/figs \_\_\_\_\_  
 the sequence listing (*specify*): \_\_\_\_\_  
 any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/012424

Box No. V      **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

## 1. Statement

Novelty (N)	Claims	1-12	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-12	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

## 2. Citations and explanations (Rule 70.7)

Document 1: WO 02/052007 A1 (Locomogene Inc.), 4 July 2002

Document 2: J. Biol. Chem., 1997, Vol. 272, No. 17, pages 11361 to 11368

Document 3: J. Biol. Chem., 1996, Vol. 271, No. 18, pages 10425 to 10428

Claims 1 to 12

The invention set forth in claims 1 to 10 does not involve an inventive step in the light of document 1 cited in the international search report.

Document 1 sets forth a gene array which codes synoviolin.

With regard to claims 1 to 10, at the time of filing of this application, having cloned a gene which codes a particular protein, it was a known technique to carry out analysis of the upstream sequence of said gene, and to determine the promoter region, therefore it would be easy for a person skilled in the art to conceive of carrying out analysis of the upstream sequence of the synoviolin gene set forth in document 1 to determine the promoter region.

The invention set forth in claims 11 and 12 does not

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International application No.	PCT/JP2004/012424
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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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involve an inventive step in the light of documents 1 to 3 cited in the international search report.

Documents 2 and 3 indicate that GABP $\alpha$ , GABP $\beta$  and Est function as transcription factors.

With regard to claims 11 and 12, it would be easy for a person skilled in the art to conceive of employing GABP $\alpha$ , GABP $\beta$ , Est and the like, which function as transcription factors for a wide variety of genes, as transcription factors for the synoviolin gene, as set forth in documents 2 and 3, and to regulate the bonding of the respective transcription factors to the promoter regions of the synoviolin gene, thereby regulating the function of said promoter.

## Supplemental Box Relating to Sequence Listing

## Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
  - a. type of material  
 a sequence listing  
 table(s) related to the sequence listing
  - b. format of material  
 in written format  
 in computer readable form
  - c. time of filing/furnishing  
 contained in the international application as filed  
 filed together with the international application in computer readable form  
 furnished subsequently to this Authority for the purposes of search and/or examination  
 received by this Authority as an amendment\* on \_\_\_\_\_
2.  In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

\* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."